

### **REMARKS**

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 33 to 53, as well as new Claim 54, the only claims pending and under examination in this application.

The Examiner is thanked for the personal interview held on May 23, 2006 with the undersigned. During the interview, the above amendments were discussed and demonstrated to overcome the rejections under 102 and 103 in the outstanding office action of February 2, 2006.

Claim 33 has been amended to indicate that the method produces a composite fixation structure at the target site. Support for this amendment is found in the specification at page 9, lines 12 ff. In addition, Claim 33 has been amended to clarify that vibration occurs during delivery of the cement (support being found in the specification at page 8, lines 7-11) and that the cement is a calcium phosphate cement (support being found in previously pending Claim 46). Claim 48 has been amended to specify that the vibratory element includes a holder for the introduction element. Support for this amendment may be found in the specification at page 22. Additional amendments have been made to various claims to clarify the claim language. Accordingly, no new matter has been added.

As no new matter is added by way of these amendments, entry thereof is respectfully requested.

### ***Claim Objections***

Claim 36 has been objected to because the claim language was assertedly unclear. Claim 36 has been amended to clarify the claim language. In view of the amendment to Claim 36 the Applicants contend that this objection has been rendered moot and respectfully request it be withdrawn.

***Claim Rejections - 35 U.S.C. § 112, second paragraph***

Claim 39 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 39 has been amended to clarify the claim language. In view of the amendment to Claim 39 the Applicants contend that this objection has been rendered moot and respectfully request it be withdrawn.

***Claim Rejections - 35 U.S.C. § 102***

Claims 33-38, 40, 41 and 46 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* (U.S. Patent No. 6,083,229).

According to the M.P.E.P. a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Additionally, the identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. § 2131.

Claim 33 is directed to a method of introducing a cement composition into a target bone site. Claims 32-38, 40, 41 and 46 all ultimately depend from and incorporate all the elements of Claim 33. Elements of Claim 33 as amended include positioning a hardware device at a target bone site and delivering a cement composition to the target site in conjunction with vibration so as to produce a composite fixation structure at said target site.

The Office asserts that Constantz discloses positioning a needle at a bone site and delivering cement to the target site by vibrating the needle. The Office is, therefore, equating the "needle" with the "hardware device" as claimed by the Applicants. The Applicants disagree and contend that a "needle" is not a "hardware device." *A needle is just a delivery tube and is never left in the body to effect fixation of bone fragments. As such, a needle is not a hardware device in the context of the claimed invention.*

However, to expedite prosecution and advance the case to issuance the Applicants have amended Claim 33 to indicate that the claimed method results in the production of a composite fixation structure at the target site.

Constantz does not teach the production of a composite fixation structure at the target site because once the cement has been delivered the delivery needle (what the office equates to the "the hardware device") is removed. Because the needle is removed a composite fixation structure is not produced.

Therefore, Constantz is deficient because it does not teach every element of the rejected claims, namely, the production of a composite fixation structure at the target site. Accordingly, because Constantz does not teach every element of the rejected claims it fails to anticipate the claimed invention. In view of the above, the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of 33-38, 40, 41 and 46 be withdrawn.

Claims 33-36, 38-39 and 43 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Olson Jr. *et al.* (U.S. Publication No. 2004/0024410).

As stated above, Claim 33 is directed to a method of introducing a cement composition into a target bone site. Claims 32-38, 40, 41 and 46 all ultimately depend from and incorporate all the elements of Claim 33. Elements of Claim 33 as amended include positioning a hardware device at a target bone site and delivering a cement composition to the target site in conjunction with vibration so as to produce a composite fixation structure at said target site.

The Office asserts that Olson discloses positioning a guidewire at a bone site and delivering cement to the target site in conjunction with vibrating the guidewire. The Office is, therefore, equating the "guidewire" with the "hardware device" as claimed by the Applicants. The Applicants disagree and contend that a "guidewire" is not a "hardware device." *A guidewire is never left in the body to effect fixation of*

*bone fragments. As such, a guidewire is not a hardware device in the context of the claimed invention.*

However, to expedite prosecution and advance the case to issuance the Applicants have amended Claim 33 to indicate that the claimed method results in the production of a composite fixation structure at the target site.

Olson does not teach the production of a composite fixation structure at the target site because, as disclosed in Olson, once the cement has been delivered the guidewire (what the office equates to "the hardware device") is removed. Because the guidewire is removed a composite fixation structure is not produced.

Therefore, Olson is deficient because it does not teach every element of the rejected claims, namely, the production of a composite fixation structure at the target site. Accordingly, because Olson does not teach every element of the rejected claims it fails to anticipate the claimed invention. In view of the above, the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of 33-38, 40, 41 and 46 be withdrawn.

Claims 48, 51 and 52 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Sproul (U.S. Patent No. 6,832,988).

Claim 48 is directed to a kit for using a bone defect filling cement. Claims 51 and 52 depend from and incorporate all the elements of Claim 48. An element of Claim 48 as amended is a vibratory element that has a holder for the introduction element. Sproul does not teach a vibratory element that has a holder for the introduction element. Accordingly, because Sproul does not teach every element of the rejected claims it fails to anticipate the claimed invention. In view of the above, the Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claims 48, 51 and 52 be withdrawn.

***Claim Rejections - 35 U.S.C. § 103***

Claims 33, 34, 37, 38 and 42-46 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Karpman *et al.* (U.S. Patent No. 6,214,012) in view of Bakels (U.S. Patent No. 4,787,751).

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claim 33 is directed to a method of introducing a cement composition into a target bone site. Claims 34, 37, 38 and 42-46 all ultimately depend from and incorporate all the elements of Claim 33. Elements of Claim 33 as amended include positioning a hardware device at a target bone site and delivering a cement composition to the target site while vibration is applied so as to produce a composite fixation structure at said target site.

The Office acknowledges that Karpman is deficient in that Karpman does not teach delivering a cement composition in conjunction with vibration. Accordingly, the Office turns to Bakels to remedy the deficiencies of Karpman. The Office asserts that Bakels discloses reducing porosity and improving fatigue strength of bone cement by vibrating a cement gun cartridge prior to placing the cartridge into the cement gun.

The Office asserts that it would have been obvious to have vibrated the bone cement cartridge in the Karpman cement gun, as taught by Bakels, prior to introduction of the cement to the target bone site so as to reduce the porosity and increase the fatigue strength of the cement.

The Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Karpman in view of Bakels fails to teach all the elements of the rejected claims. As set forth above, an element of the claims is the delivery of a cement composition to a target bone site while vibration is applied. As such, the claimed method requires that vibration is applied concurrently with the delivery of the cement composition to the target bone site. Neither Karpman nor Bakels teach or suggest the concurrent application of vibration with the delivery of the cement composition to the target bone site. Karpman does not teach or suggest this element because it is completely silent as to the use of vibration. Bakels does not teach or suggest this element because Bakels only teaches the use of vibration during the process of filling the cement gun cartridge and is completely silent as to applying vibration during the actual delivery of the cement. See column 5, line 30 to column 6, line 5.

In view of the above, neither Karpman nor Bakels teaches or suggest all the elements of the rejected claims, namely, delivering a cement composition to the target bone site in conjunction with vibration. Accordingly, because the recited combination fails to teach every element of the rejected claims a *prima facie* case of obviousness has not been established. The Applicants, therefore, respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 33, 34, 37, 38 and 42-46 be withdrawn.

Claim 39 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* (U.S. Patent No. 6,083,229) in view of Olson Jr. *et al.* (U.S. Publication No. 2004/0024410).

Claim 39 depends from Claim 33. An element of Claim 33 as amended is producing a composite fixation structure at a target site. As set forth above, neither Constantz nor Olson teach or suggest this element. Constantz does not teach or suggest this element because Constantz actually teaches removing the needle (e.g., "hardware device") during and after the delivery of the cement. See column 27, lines

17 to 21. Hence, a composite fixation structure is not produced. Olson does not teach this element because Olson does not teach the production of a structure in the first place, let alone a composite fixation structure. Accordingly, a *prima facie* case of obviousness has not been established because the combination of Constantz in view of Olson fails to teach all the elements of the rejected claims. Therefore, in view of the above, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 39 be withdrawn.

Claim 47 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Olson Jr. *et al.* (U.S. Publication No. 2004/0024410) in view of Bakels (U.S. Patent No. 4,787,751).

Claim 47 depends from Claim 33. An element of Claim 33 as amended is producing a composite fixation structure at a target site. Neither Olson nor Bakels teach or suggest this element. Olson does not teach this element because Olson does not teach the production of a structure in the first place, let alone a composite fixation structure. Hence, a composite fixation structure is not produced. Bakels does not teach this element because Bakels is simply directed to a bone cement mixing device and is completely silent as to the use of a hardware device so as to produce a composite fixation structure. Accordingly, a *prima facie* case of obviousness has not been established because the combination of Olson in view of Bakels fails to teach all the elements of the rejected claims. Therefore, in view of the above, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 47 be withdrawn.

Claim 49 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sproul (U.S. Patent No. 6,832,988) in view of Constantz *et al.* (U.S. Patent No. 6,083,229). As reviewed above in connection with the discussion of Claim 48, Sproul fails to teach or suggest a vibratory element that has a holder for the cement introduction element. As Constantz was cited solely for the teaching of a two-component cement, Constantz fails to make up this deficiency in Sproul.

Therefore, in view of the above, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claim 49 be withdrawn.

Claims 50 and 53 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sproul (U.S. Patent No. 6,832,988) in view of Karpman *et al.* (U.S. Patent No. 6,214,012).

Claims 50 and 53 depend from Claim 48. As reviewed above in connection with the discussion of Claim 48, Sproul fails to teach or suggest a vibratory element that has a holder for a cement introduction element. As Karpman was cited solely for its disclosure of hardware components, it fails to remedy the deficiencies of Sproul. Accordingly, a *prima facie* case of obviousness has not been established because the combination of Sproul in view of Karpman fails to teach all the elements of the rejected claims. Therefore, in view of the above, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 50 and 53 be withdrawn.



**CONCLUSION**

In view of the amendments and arguments above, Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at (650) 327 3400.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,

Date: June 1, 2006

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